

CLAIMS

We claim:

1 1. A method of treating an inflammatory disease or inflammatory disorder in a
2 person in need thereof comprising administering an anti-tumor necrosis factor alpha antibody
3 Fab' fragment CDP870 and at least one disease modifying anti-rheumatic drug to the person in a
4 therapeutically effective amount.

1 2. The method of claim 1 wherein the disease modifying anti-rheumatic drug is
2 methotrexate.

1 3. The method of claim 1 wherein the disease modifying anti-rheumatic drug is
2 sulfasalazine.

1 4. A method of treating arthritis in a person in need thereof comprising
2 administering an anti-tumor necrosis factor alpha antibody Fab' fragment CDP870 and at least
3 one disease modifying anti-rheumatic drug to the person in a therapeutically effective amount.

1 5. The method of claim 4 wherein the disease modifying anti-rheumatic drug is
2 methotrexate.

1 6. The method of claim 4 wherein the disease modifying anti-rheumatic drug is
2 sulfasalazine.

1 7. A method of treating rheumatoid arthritis in a person in need thereof comprising
2 administering an anti-tumor necrosis factor alpha antibody Fab' fragment CDP870 and at least
3 one disease modifying anti-rheumatic drug to the person in a therapeutically effective amount.

1 8. The method of claim 7 wherein the disease modifying anti-rheumatic drug is
2 methotrexate.

1 9. The method of claim 7 wherein the disease modifying anti-rheumatic drug is
2 sulfasalazine.

1 10. A method of treating inflammatory disease or disorder in a person in need thereof
2 comprising co-administering an anti-tumor necrosis factor alpha antibody Fab' fragment
3 CDP870 and at least one disease modifying anti-rheumatic drug to the person in a therapeutically
4 effective amount.

1 11. The method of claim 10 wherein the disease modifying anti-rheumatic drug is
2 methotrexate.

1 12. The method of claim 10 wherein the disease modifying anti-rheumatic drug is
2 sulfasalazine.

1 13. A method of treating arthritis in a person in need thereof comprising co-
2 administering an anti-tumor necrosis factor antibody Fab' fragment CDP870 and at least one
3 disease modifying anti-rheumatic drug to the individual in a therapeutically effective amount.

1 14. The method of claim 13 wherein the disease modifying anti-rheumatic drug is
2 methotrexate.

1 15. The method of claim 13 wherein the disease modifying anti-rheumatic drug is
2 sulfasalazine.

1 16. A method of treating rheumatoid arthritis in a person in need thereof comprising
2 co-administering an anti-tumor necrosis factor alpha antibody Fab' fragment CDP870 and at
3 least one disease modifying anti-rheumatic drug to the person in a therapeutically effective
4 amount.

1 17. The method of claim 16 wherein the disease modifying anti-rheumatic drug is
2 methotrexate.

1 18. The method of claim 16 wherein the disease modifying anti-rheumatic drug is
2 sulfasalazine.

1 19. A method of treating an inflammatory disease or disorder in a person in need
2 thereof comprising sequentially administering an anti-tumor necrosis factor alpha antibody and
3 sulfasalazine to the person in a therapeutically effective amount.

1 20. The method of claim 19 wherein the inflammatory disease is arthritis.

1 21. The method of claim 19 wherein the inflammatory disease is rheumatoid arthritis.

1 22. A method of treating arthritis in a person in need thereof comprising sequentially
2 administering an anti-tumor necrosis factor alpha antibody Fab' fragment CDP870 and at least
3 one disease modifying anti-rheumatic drug to the person in a therapeutically effective amount.

1 23. The method of claim 22 wherein the disease modifying anti-rheumatic drug is
2 methotrexate.

1 24. The method of claim 22 wherein the disease modifying anti-rheumatic drug is
2 sulfasalazine.

1 25. A method of treating rheumatoid arthritis in a person in need thereof comprising
2 sequentially administering an anti-tumor necrosis factor alpha antibody Fab' fragment CDP870
3 and at least one disease modifying anti-rheumatic drug to the person in a therapeutically effective
4 amount.

1 26. The method of claim 25 wherein the disease modifying anti-rheumatic drug is
2 methotrexate.

1 27. The method of claim 25 wherein the disease modifying anti-rheumatic drug is
2 sulfasalazine.

1 28. A method for treatment, prevention or inhibition of inflammation or
2 inflammation-related disorder in a person in need of such treatment, prevention or inhibition, the
3 comprising treating the person with an anti-tumor necrosis factor alpha antibody Fab' fragment
4 CDP 870 and a disease modifying anti-rheumatic drug in a therapeutically effective amount.

1 29. The method of claim 28 wherein the disease modifying anti-rheumatic drug is
2 methotrexate.

1 30. The method of claim 28 wherein the disease modifying anti-rheumatic drug is
2 sulfasalazine.

1 31. A method for treatment, prevention or inhibition of rheumaty arthritis or a
2 related disorder, or inflammation-associated with rheumaty arthritis in a person in need of such
3 treatment, prevention or inhibition, the comprising the step of treating the person with an anti-
4 tumor necrosis factor alpha antibody Fab' fragment CDP 870 and a disease modifying anti-
5 rheumatic drug in a therapeutically effective amount.

1 32. The method of claim 31 wherein the disease modifying anti-rheumatic drug is
2 methotrexate.

1 33. The method of claim 31 wherein the disease modifying anti-rheumatic drug is
2 sulfasalazine.

1 34. A composition for the treatment, prevention, or inhibition of inflammation, or
2 inflammation-associated disorder comprising an anti-tumor necrosis factor alpha antibody Fab'
3 fragment CDP 870 and a disease modifying anti-rheumatic drug.

1 35. The composition of claim 34 wherein the disease modifying anti-rheumatic drug
2 is methotrexate.

1 36. The composition of claim 34 wherein the disease modifying anti-rheumatic drug
2 is sulfasalazine.

1 37. A composition for the treatment, prevention or inhibition or pain of rheumatoid
2 arthritis or rheumatoid arthritis associated disorder comprising an anti-tumor necrosis factor
3 alpha antibody Fab' fragment CDP 870 and a disease modifying anti-rheumatic drug.

1 38. The composition of claim 37 wherein the disease modifying anti-rheumatic drug
2 is methotrexate.

1 39. The composition of claim 37 wherein the disease modifying anti-rheumatic drug
2 is sulfasalazine.

1 40. A kit that is suitable for use in the treatment, prevention or inhibition of pain,
2 inflammation or inflammation-associated disorder comprising a first dosage form of an anti-
3 tumor necrosis factor alpha antibody Fab' fragment CDP 870 and a second dosage form of a
4 disease modifying anti-rheumatic drug, said first dosage form and said second dosage form
5 provided in quantities which comprise a therapeutically effect amount of the compounds for the
6 treatment, prevention or inhibition of cardiovascular disease or disorder.

1 41. The kit of claim 40 wherein the disease modifying anti-rheumatic drug is
2 methotrexate.

1 42. The kit of claim 42 wherein the disease modifying anti-rheumatic drug is
2 sulfasalazine.

1 43. A kit that is suitable for use in the treatment, prevention or inhibition of
2 rheumatoid arthritis or a rheumatoid arthritis-associated disorder comprising a first dosage form
3 of an anti-tumor necrosis factor alpha antibody Fab' fragment CDP 870 and a second dosage
4 form of a disease modifying anti-rheumatic drug, said first dosage form and said second dosage
5 form provided in quantities which comprise a therapeutically effect amount of the compounds
6 for the treatment, prevention or inhibition of cardiovascular disease or disorder.

1 44. The kit of claim 43 wherein the disease modifying anti-rheumatic drug is
2 methotrexate.

1 45. The kit of claim 43 wherein the disease modifying anti-rheumatic drug is
2 sulfasalazine.

1 46. A kit that is suitable for use in the treatment, prevention or inhibition of pain,
2 inflammation or inflammation-associated disorder comprising a dosage form of an anti-tumor
3 necrosis factor alpha antibody Fab' fragment CDP 870 and a disease modifying anti-rheumatic
4 drug wherein said dosage form is provided in quantities which comprise a therapeutically effect
5 amount of the compounds for the treatment, prevention or inhibition of cardiovascular disease or
6 disorder.

1 47. The kit of claim 46 wherein the disease modifying anti-rheumatic drug is
2 methotrexate.

1 48. The kit of claim 46 wherein the disease modifying anti-rheumatic drug is
2 sulfasalazine.

1 49. A method of treating an inflammatory disease or inflammatory disorder in a
2 person in need thereof comprising:

- 3 (a) preparing a therapeutic composition comprising a therapeutically effective
- 4 amount of an anti-tumor necrosis factor alpha antibody Fab' fragment
- 5 CDP870 and at lease one disease modifying anti-rheumatic drug; and
- 6 (b) administering in a repetitive dosing regimen the therapeutic composition
- 7 to the person.

1 50. The method of claim 49 wherein the repetitive dosing regimen of the anti-tumor
2 necrosis factor alpha antibody Fab' fragment CDP870 is about once every four weeks.

1 51. The method of claim 50 wherein the therapeutic effective amount of the anti-
2 tumor necrosis factor alpha antibody Fab' fragment CDP870 is about 200 mg to about 800 mg.

1 52. The method of claim 50 wherein the therapeutic effective amount of the anti-
2 tumor necrosis factor alpha antibody Fab' fragment CDP870 is about 400 mg.

1 53. The method of claim 49 wherein the disease modifying anti-rheumatic is
2 methotrexate.

1 54. The method of claim 53 wherein the repetitive dosing regimen of the
2 methotrexate is about once every week.

1 55. The method of claim 54 wherein the therapeutic effective amount of methotrexate
2 is about 2.5 mg to about 50 mg.

1 56. The method of claim 54 wherein the therapeutic effective amount of the
2 methotrexate is about 7.5 mg to about 15 mg.

1 57. The method of claim 49 wherein the disease modifying anti-rheumatic is
2 sulfasalazine.

1 58. The method of claim 57 wherein the repetitive dosing regimen of the sulfasalazine
2 is about once every day.

1 59. The method of claim 58 wherein the therapeutic effective amount of sulfasalazine
2 is about 0.5 g to about 3 g.

1 60. The method of claim 58 wherein the therapeutic effective amount of the
2 methotrexate is about 2 g to about 3 g.

1 61. A method of modulating an inflammatory disease or inflammatory disorder in a
2 person in need thereof comprising administering an anti-tumor necrosis factor alpha antibody
3 Fab' fragment CDP870 and at least one disease modifying anti-rheumatic drug to the person in a
4 therapeutically effective amount.

1 62. The method of claim 61 wherein the disease modifying anti-rheumatic drug is
2 methotrexate.

1 63. The method of claim 61 wherein the disease modifying anti-rheumatic drug is
2 sulfasalazine.

1 64. A method of modulating arthritis in a person in need thereof comprising
2 administering an anti-tumor necrosis factor alpha antibody Fab' fragment CDP870 and at least
3 one disease modifying anti-rheumatic drug to the person in a therapeutically effective amount.

1 65. The method of claim 64 wherein the disease modifying anti-rheumatic drug is
2 methotrexate.

1 66. The method of claim 64 wherein the disease modifying anti-rheumatic drug is
2 sulfasalazine.

1 67. A method of modulating rheumatoid arthritis in a person in need thereof
2 comprising administering an anti-tumor necrosis factor alpha antibody Fab' fragment CDP870
3 and at least one disease modifying anti-rheumatic drug to the person in a therapeutically effective
4 amount.

1 68. The method of claim 67 wherein the disease modifying anti-rheumatic drug is
2 methotrexate.

1 69. The method of claim 67 wherein the disease modifying anti-rheumatic drug is
2 sulfasalazine.

1 70. A method of modulating inflammatory disease or disorder in a person in need
2 thereof comprising co-administering an anti-tumor necrosis factor alpha antibody Fab' fragment
3 CDP870 and at least one disease modifying anti-rheumatic drug to the person in a therapeutically
4 effective amount.

1 71. The method of claim 70 wherein the disease modifying anti-rheumatic drug is
2 methotrexate.

1 72. The method of claim 70 wherein the disease modifying anti-rheumatic drug is
2 sulfasalazine.

1 73. A method of modulating arthritis in a person in need thereof comprising co-
2 administering an anti-tumor necrosis factor antibody Fab' fragment CDP870 and at least one
3 disease modifying anti-rheumatic drug to the individual in a therapeutically effective amount.

1 74. The method of claim 73 wherein the disease modifying anti-rheumatic drug is
2 methotrexate.

1 75. The method of claim 73 wherein the disease modifying anti-rheumatic drug is
2 sulfasalazine.

1 76. A method of modulating rheumatoid arthritis in a person in need thereof
2 comprising co-administering an anti-tumor necrosis factor alpha antibody Fab' fragment
3 CDP870 and at least one disease modifying anti-rheumatic drug to the person in a therapeutically
4 effective amount.

1 77. The method of claim 76 wherein the disease modifying anti-rheumatic drug is
2 methotrexate.

1 78. The method of claim 76 wherein the disease modifying anti-rheumatic drug is
2 sulfasalazine.

1 79. A method of modulating an inflammatory disease or disorder in a person in need
2 thereof comprising sequentially administering an anti-tumor necrosis factor alpha antibody and
3 sulfasalazine to the person in a therapeutically effective amount.

1 80. The method of claim 79 wherein the inflammatory disease is arthritis.

1 81. The method of claim 79 wherein the inflammatory disease is rheumatoid arthritis.

1 82. A method of modulating arthritis in a person in need thereof comprising
2 sequentially administering an anti-tumor necrosis factor alpha antibody Fab' fragment CDP870
3 and at least one disease modifying anti-rheumatic drug to the person in a therapeutically effective
4 amount.

1 83. The method of claim 82 wherein the disease modifying anti-rheumatic drug is
2 methotrexate.

1 84. The method of claim 82 wherein the disease modifying anti-rheumatic drug is
2 sulfasalazine.

1 85. A method of modulating rheumatoid arthritis in a person in need thereof
2 comprising sequentially administering an anti-tumor necrosis factor alpha antibody Fab'
3 fragment CDP870 and at least one disease modifying anti-rheumatic drug to the person in a
4 therapeutically effective amount.

1 86. The method of claim 85 wherein the disease modifying anti-rheumatic drug is
2 methotrexate.

1 87. The method of claim 85 wherein the disease modifying anti-rheumatic drug is
2 sulfasalazine.